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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,263	01/26/2001	Gale Arthur Granger	IRVN-005CIP	7988

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,263

Applicant(s)

THOMPSON ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-26 is/are pending in the application.
- 4a) Of the above claim(s) 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-15, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 12/03/2003 is acknowledged and entered into the record. Accordingly, claim 1 is canceled without prejudice or disclaimer. Claims 16-24 are withdrawn from further consideration as being drawn to a non-elected invention.
2. Claims 2-15, and 25-26 are examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Double Patenting

4. The rejection of claims 2,5,6-7,9,11,13,14, 15, 25, and 26 under the judicially created doctrine of obvious type double patenting is maintained for the reasons of record. It is noted that applicant states that a terminal disclaimer will be filed upon notice of allowable subject matter.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 2-5, 8-12 and 25 under 35 USC 102 (b) as being anticipated by Kohler *et al* is maintained for the reasons of record. Applicant argues that the cited reference fails to teach each and every limitation of the claimed invention, specifically that the claims as now amended recites the limitation of being "formulated for administration into a solid tumor or the bed of a solid tumor." However, the recited limitation fails to distinguish the composition taught by Kohler *et al* from that instantly claimed. Moreover, the intended use of administration into a tumor does not breath any patentable weight into the claimed invention. Furthermore, because the patent office

does not have the facilities to determine that the composition taught by Kohler *et al* would *not* work if administered into the tumor, in the absence of evidence to the contrary, the amount of cell administered and route of administration taught by Kohler *et al* fails to differentiate the composition of the instant invention from that taught by Kohler *et al*.

The applicant further argues that the amendment of the claims to recite lymphocytes from an unrelated donor differentiates the instant invention from that of Kohler *et al*. Applicant's arguments have been considered but are not deemed persuasive because Kohler *et al* teach a "pool" of allo-activated peripheral blood lymphocytes (PBL) that comprises a haploidentical lymphocytoid from a donor. Because the "pool" of PBLs are from 10 unrelated donors and because the exposure of at least two of the unrelated or allogeneic populations of lymphocytes within the pool initiates the transformation of the lymphocytes (i.e. alloactivation), the composition taught by Kohler *et al* anticipates claims that read on alloactivated lymphocytes from unrelated donors.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 2,8-13, and 25 under 35 USC 102(b) as being anticipated by Philips *et al* is maintained for the reasons of record. Applicant argues that the use of a pharmaceutical excipient is a required component of the claimed invention and that because Philips *et al* fails to teach the use of a required component, and fails to suggest a use of a required component, the reference fails to anticipate the instant invention.

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Contrary to what applicant has argued, Philips *et al* does in fact teach the use of a pharmaceutical excipient. The population of cells taught by Philips *et al* were resuspended in a solution of Hanks balanced salt solution (HBSS). HBSS has been shown, (as evidenced by Puri RK *et al* Cancer Immunol Immunother. 1989;28(4):267-74.) to be used in vivo as a control solution, thereby qualifying it as a pharmaceutical excipient.

Claim Rejections Maintained - 35 USC § 103

7. The rejection of claims 13 under 35 USC 103(a) as being anticipated by Kohler *et al* in view of Philips *et al* is maintained for the reasons of record. Applicant's arguments are substantially identical to the arguments made for both 102(b) rejections rebutted above.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 12/03/2003.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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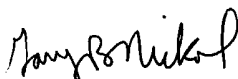
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
March 2, 2004


GARY NICKOL
PRIMARY EXAMINER